

Declaration of Conformity

Application of Council Directive(s): Medical Device Directive 93/42/EEC

Standards to which Conformity is Declared: EN ISO 13485, EN ISO 10993, EN ISO 11135, EN ISO 11607, ISO 14644, EN ISO 14971, EN 868, EN 1041, EN 980, EN ISO 105223-1

Manufacturer's Name: CooperSurgical, Inc.

Manufacturer's Address: 95 Corporate Drive, Trumbull, CT 06611 USA

Authorized European Representative: EMERGO EUROPE, Prinsessegracht 20
2514 AP The Hague, The Netherlands

Notified Body: BSI (British Standards Institute) NB number: 2797
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands
Applies to Annex V Only

Type of Equipment: Vacuum Assisted Delivery Devices and Accessories

Conformity Assessment: Annex V (CE 69386) and Annex VII of MDD 93/42/EEC

Device classification per MDD 93/42/EEC: Class IIa, Rule 6

Model Numbers: 10004, 10007LP, 10008, 10015LP, 10020, 10021, 10137, 10500, 10022, 10057, 10058, 10067, 10068

Date of First Issue: February 19, 2004

We hereby declare that the equipment specified above conforms to the above Directive(s) and Standard(s).

Rev. H: Update Standards. Added P/Ns: 10067 and 10068. Update J. Chris Jensen's position title to Senior level. (10/25/2016)
 Rev. I: Update Standards, update EMERGO address, expand to list Model Numbers and Descriptions on Page 2. (5/22/2017)
 Rev. J: Adjust Font Sizing (06/19/2017)
 Rev. K: Reinstate Annex VII in addition to Annex V in the Conformity Assessment. 8/28/2017
 Rev. L: Add Notified Body number 0086 and CE certificate number. 06/29/2018
 Rev. M: Change BSI Notified Body from UK to The Netherlands. Add "Applies to Annex V Only." - 02/25/2019
 Rev. N: Removal of ISO 11137. - 10/14/2019

 Oct. 14 2019
 (Signature) (date)

J. Chris Jensen
 (Full Name)

Senior Director, Regulatory Affairs and Compliance
 (Position)

Vacuum-Assist Delivery Devices and Accessories

Cooper Surgical, Inc. 95 Corporate Drive, Trumbull, CT 06611 USA

Phone: (203) 601-5200 Fax: (203) 601-9870

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Model Number	Model Name
10004	Mityvac® Pearl Edge® Bell Cup, Sterile Quantity: 1 Box (12 Units)
10007LP	Mityvac® M-Style® Mushroom Cup, Sterile Quantity: 1 Box (12 Units)
10008	Mityvac® Super M-Style® Mushroom Cup, Sterile Quantity: 1 Box (12 Units)
10015LP	Mityvac® M-Style® Mushroom Cup with Universal Vacuum Release (UVR) , Sterile Quantity: 1 Box (12 Units)
10020	Mityvac® MitySoft® Bell Cup, Sterile Quantity: 1 Box (12 Units)
10021	Mityvac® MitySoft® Bell Cup with Universal Vacuum Release (UVR) , Sterile Quantity: 1 Box (12 Units)
10137	Mityvac® M-Select® Mushroom Cup, Sterile Quantity: 1 Box (12 Units)
10500	Mityvac® Reusable Vacuum Extraction Cup, Non-sterile Quantity: 1
10022	Mityvac® Reusable Obstetrical Vacuum Pump, Non-sterile Quantity: 1
10057	Mystic® II Mityvac® M-Style® Mushroom Cup, Sterile Quantity: 1 Box (12 Units)
10058	Mystic® II Mityvac® MitySoft® Bell Cup, Sterile Quantity: 1 Box (12 Units)
10067	MityOne® Pump with M-Style® Mushroom Cup, Sterile Quantity: 1 Box (12 Units)
10068	MityOne® Pump with MitySoft® Bell Cup, Sterile Quantity: 1 Box (12 Units)